UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,687	03/21/2005	Marie-Christine Wolf	PA/4-32689A	4645

67283 7590 04/10/2009

MONTGOMERY, MCCRACKEN, WALKER & RHOADS, LLP
123 SOUTH BROAD STREET
AVENUE OF THE ARTS
PHILADELPHIA, PA 19109

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,687	WOLF ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,8-12 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6,8-12 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 01/21/09 are acknowledged.

2. Claims 1-3, 5, 7, and 13-15 were cancelled. Claims 4, 6, 8-11, and 16-17 were amended. Claims 16-17 were withdrawn from consideration.

3. Claims 4, 6, 8-12, and 18 are included in the prosecution.

Response to Arguments

Rejection of claims 1-4, 6 and 13 under 35 USC § 102(b)

4. In light of Applicants' cancellation of claims 1-3 and 13, the rejection with respect to these claims is rendered moot.

5. Applicants' arguments, see Page 5, filed 01/21/09, with respect to the rejection of claims 4 and 6 under 35 USC § 102(b) as being anticipated by Katzhendler et al. (US 6,296,873) have been fully considered but are not persuasive.

Applicants argue that Katzhendler does not teach each and every element of Applicant's claims as amended, and more specifically, Katzhendler does not teach an oral dosage form of oxcarbazepine which can be administered once per day and which produces constant plasma levels of the monohydroxy derivate of oxcarbazepine (10,11 -dihydro-10-hydroxy-5H- dibenz[b,f]azepine-5-carboxamide, referred to as MHD) over a twenty-four (24) hour period. Applicants argue that "Zero-order kinetics" mentioned in Katzhendler does not teach constant-plasma levels of monohydroxy derivate over 24 hours, that zero-order kinetics simply means the rate of reaction is a constant. Applicants argue that there is no teaching in Katzhendler that kinetics occur over and up

to 24 hours and that once a day is not the same as constant level in plasma over 24 hours.

This is not persuasive because Katzhendler discloses the monohydroxy derivate of oxcarbazepine (10,11 -dihydro-10-hydroxy-5H- dibenz[b,f]azepine-5-carboxamide) (Col. 3, lines 64-65). Katzhendler teaches that "zero-order release kinetics" means a constant, linear, continuous, sustained and controlled release rate of carbamazepine or a carbamazepine derivative from polymer matrix (Col. 3, lines 51-55). The further excipient (cellulose ether) is also disclosed and the ratio of the polymer:drug is disclosed as including 5:95%, which is 1:19%, which anticipates the instantly claimed range of excipient:drug in new claim 18 (from about 1:10 to about 1:20) (Col. 8, lines 30-32). Katzhendler teaches administering the formulation once per day (Col. 11, lines 31-32). Since the components of the composition (drug, excipient, ratio of excipient:drug) and the administration of the composition (once per day) as taught by Katzhendler are the same as recited in new claim 18, the limitation of the constant MHD plasma levels over 24 hours in a patient is anticipated by Katzhendler. The constant MHD plasma levels are an intrinsic property of the composition comprising the specific monohydroxy derivate of oxcarbazepine (10,11 -dihydro-10-hydroxy-5H- dibenz[b,f]azepine-5-carboxamide) in a specific weight ratio with a cellulose ether excipient when the composition is administered once per day with constant release of the carbamazepine derivative.

"A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." Please see MPEP 2112.01.

Therefore, the rejection of 04/30/08 is maintained with respect to claims 4 and 6 and applied to new claim 18. Since the inclusion of claim 18 in the rejection was necessitated by Applicants' amendment, this rejection is made FINAL.

Rejection of claims 3-4 and 9 under 35 USC § 102(b)

6. In light of Applicants' cancellation of claim 3, the rejection with respect to this claim is rendered moot.

7. Applicants' arguments, see Page 9, filed 01/21/09, with respect to the rejection of claims 4 and 9 under 35 USC § 102(b) as being anticipated by Borquin (US 5,695,782) have been fully considered and are persuasive in light of Applicants' amendments. Therefore, the rejection is withdrawn.

Rejection of claims 3-4 and 9 under 35 USC § 102(b)

8. In light of Applicants' cancellation of claim 3, the rejection with respect to this claim is rendered moot.

9. Applicants' arguments, see Page 10, filed 01/21/09, with respect to the rejection of claims 4 and 9 under 35 USC § 102(b) as being anticipated by Schlütermann (WO 98/35681) have been fully considered and are persuasive in light of Applicants' amendments. Therefore, the rejection is withdrawn.

Rejection of claims 3-4 and 9 under 35 USC § 102(b)

10. In light of Applicants' cancellation of claim 3, the rejection with respect to this claim is rendered moot.

11. Applicants' arguments, see Page 11, filed 01/21/09, with respect to the rejection of claims 4 and 9 under 35 USC § 102(b) as being anticipated by Lang (WO 01/32183)

have been fully considered and are persuasive in light of Applicants' amendments. Therefore, the rejection is withdrawn.

Rejection of claims 5, 7 and 10-12 under 35 USC § 103(a)

12. In light of Applicants' cancellation of claims 5 and 7, the rejection with respect to these claims is rendered moot.

13. Applicants' arguments, see Page 12, filed 01/21/09, with respect to the rejection of claims 10-12 under 35 USC § 103(a) as being unpatentable over Katzhendler et al. (US 6,296,873) have been fully considered but are not persuasive.

Applicants argue that the most preferable polymer to drug ratios disclosed in Katzhendler are from 10:90 to about 80:20, which are outside the present invention and teach away from the weight ratio claimed by the Applicants.

This is not persuasive because Katzhendler teaches the ratio of the polymer:drug as including 5:95%, which is 1:19%. This ratio of 1:19% renders the instantly claimed range of excipient:drug in new claim 18 (from about 1:10 to about 1:20) obvious(Col. 8, lines 30-32). The limitations of new claim 18 are taught by Katzhendler, and one of ordinary skill in the art would find it obvious to test the composition based on the standard in vitro dissolution tests of oxcarbazepine during the process of routine experimentation in order to optimize the desired release and pharmacokinetic profile of the composition.

Therefore, the rejection of 04/30/08 is maintained with respect to claims 10-12.

Rejection of claim 8 under 35 USC § 103(a)

14. Applicants' arguments, see Page 13, filed 01/21/09, with respect to the rejection of claim 8 under 35 USC § 103(a) as being unpatentable over Katzhendler et al. (US

6,296,873) in view of Eibl et al. (US 5,290,769) have been fully considered but are not persuasive.

Applicants argue that the most preferable polymer to drug ratios disclosed in Katzhendler are from 10:90 to about 80:20, which are outside the present invention and teach away from the weight ratio claimed by the Applicants.

This is not persuasive because Katzhendler teaches the ratio of the polymer:drug as including 5:95%, which is 1:19%. This ratio of 1:19% renders the instantly claimed range of excipient:drug in new claim 18 (from about 1:10 to about 1:20) obvious(Col. 8, lines 30-32). The limitations of new claim 18 are taught by Katzhendler, and one of ordinary skill in the art would find it obvious to test the composition based on the standard in vitro dissolution tests of oxcarbazepine during the process of routine experimentation in order to optimize the desired release and pharmacokinetic profile of the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a sustained release tablet of oxcarbazepine with methacrylic acid derivatives, as suggested by Katzhendler, and combine it with the copolymerizates of acrylic acid and methacrylic acid esters and trimethylammonium methacrylate (for example EUDRAGIT ® RL), as suggested by Eibl, with a reasonable expectation of producing a sustained release tablet of oxcarbazepine. One of ordinary skill in the art would have done so because copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate are known in the art as coating substances that are used in the production of delayed or sustained release dosage forms.

Therefore, the rejection of 04/30/08 is maintained.

Provisional Rejection of claims 1-13 under nonstatutory obviousness-type double patenting

15. In light of Applicants' cancellation of claims 1-3, 5, 7, and 13, the rejections with respect to these claims is rendered moot.

16. Applicants' arguments, see Page 14, filed 01/21/09, with respect to the provisional rejection of claims 4, 6, and 8-12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 12-13 and 15-16 of copending Application No. 10/598,553 in view of Katzhendler et al. (US 6,296,873) have been fully considered but are not persuasive. Applicants did not point out that the obviousness-type double patenting rejection was improper. Applicants must point out the reasons why the obviousness-type double patenting rejection is improper or file a terminal disclaimer in order to be responsive. Until such time that a terminal disclaimer is filed, the obviousness-type double patenting rejection of 04/30/08 will be maintained.

17. Applicants' arguments, see Page 15, filed 01/21/09, with respect to the provisional rejection of claims 4, 6, and 8-12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-7 and 9-12 of copending Application No. 10/598,786 in view of Katzhendler et al. (US 6,296,873) have been fully considered but are not persuasive. Applicants did not point out that the obviousness-type double patenting rejection was improper. Applicants must point out the reasons why the obviousness-type double patenting rejection is improper or file a

terminal disclaimer in order to be responsive. Until such time that a terminal disclaimer is filed, the obviousness-type double patenting rejection of 04/30/08 will be maintained.

Claim Objections

18. Claims 4, 6, and 8-11 are objected to under 37 CFR 1.75(c) as being in improper form because they are not dependent on a preceding claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 4, 6 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Katzhendler et al. (US 6,296,873).

The claimed invention is an oral dosage form, comprising: a tablet core and a coating wherein the core comprises oxcarbazepine, optionally, a filler, and at least one further excipient selected from the group comprising cellulose ethers, carboxyvinyl polymer of acrylic acid cross linked with alkyl ethers of sucrose, carboxyvinyl polymer of acrylic acid cross linked with pentaerythritol, and polymethacrylates, wherein the weight ratio of the excipient to oxcarbazepine is from about 1:10 to about 1:20, wherein when administered once a day to a patient, is released to produce constant MHD plasma levels over 24 hours in said patient.

Katzhendler teaches “a controlled and sustained release oral drug delivery system comprising carbamazepine or a carbamazepine derivative. Carbamazepine or the derivative thereof is formulated within a polymeric matrix, said matrix optionally

further containing additional pharmaceutically acceptable constituents and additives. The polymer in the polymeric matrix permits carbamazepine or its derivative to be released from the matrix by zero-order release kinetics" (Col. 6, lines 21-29). Oxcarbazepine (10,11-dihydro-10-oxo-5H-dibenz/b,f/azepine-5-carboxamide) is disclosed as a carbamazepine derivative that is used as the pharmaceutically active agent in the drug delivery system (Col. 3, lines 57-63). The mono hydroxy derivative (MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) is also disclosed (Col. 3, lines 64-65). The polymer component of the drug delivery system comprises at least one hydrophilic polymer (Col. 8, lines 23-26) such as hydrophilic cellulose derivatives (Col. 8, lines 41-43). Hydroxypropyl methylcellulose (HPMC) is disclosed as a preferred hydrophilic cellulose derivative (Col. 8, lines 52-54). "Polymers are mixed with drug in a weight ratio of polymer to drug from about 1:99% to about 99:1%, preferably from about 5:95% (calculated to be 1:19%) to about 90:10%, most preferably from about 10:90% to about 80:20%, depending on the viscosity grade of the polymer, on the tablet dimension and shape and on the desired release rate" (Col. 8, lines 30-35). The erodible tablet form of the drug/matrix is disclosed (Col. 9, lines 25-27). The ratio of "drug : polymer is varied depending on the size and shape of the tablet, on the drug amount and drug release rate, and depends also on the molecular weight and viscosity grade of the polymer …" (Col. 9, lines 28-34). Katzhendler also teaches that the polymeric matrix of the drug delivery may also contain a hydrophobic polymer such as ethylcellulose and methacrylic acid derivatives (Col. 9, lines 45-52). "The hydrophobic polymer is added to the hydrophilic polymer in amount from about 0.1 to about 10%, preferably from about 1% to about 5%, of the total

polymer. Ratios of hydrophilic to hydrophobic polymer are from about 99.9:0.1 to about 90:10, preferably from about 99:1 to about 95:5" (Col. 9, lines 63-65). Tablets that may be coated with pharmaceutically acceptable coatings are disclosed (Col. 10, lines 60-67). The carbamazepine derivative is delivered once a day (Col. 11, lines 31-32).

Regarding instant claim 18, the limitation of an oral dosage form, comprising: a tablet core and a coating wherein the core comprises oxcarbazepine, and at least one further excipient selected from the group comprising cellulose ethers, carboxyvinyl polymer of acrylic acid cross linked with alkyl ethers of sucrose, carboxyvinyl polymer of acrylic acid cross linked with pentaerythritol, and polymethacrylates, is anticipated by the oral drug delivery system comprising oxcarbazepine (10,11-dihydro-10-oxo-5H-dibenz/b,f/azepine-5-carboxamide) (Col. 3, lines 57-63) and the polymeric matrix including cellulose derivatives such as HPMC (Col. 8, lines 52-54), as taught by Katzhendler. The limitation of the weight ratio of the excipient to oxcarbazepine that is from about 1:10 to about 1:20 is anticipated by the ratio of the polymer:drug including 5:95%, (which is calculated to be 1:19%), as taught by Katzhendler (Col. 8, lines 30-32). The limitation of the oral dosage form when administered once a day to a patient, is released to produce constant MHD plasma levels over 24 hours in said patient is anticipated by the oral drug delivery system of Katzhendler that is administered once per day (Col. 11, lines 31-32). Since the components of the composition (drug, excipient, ratio of excipient:drug) and the administration of the composition (once per day) as taught by Katzhendler are the same as recited in new claim 18, the limitation of the constant MHD plasma levels over 24 hours in a patient is anticipated by Katzhendler. The constant MHD plasma levels are an intrinsic property of the

composition comprising the specific monohydroxy derivate of oxcarbazepine (10,11 - dihydro-10-hydroxy-5H- dibenz[b,f]azepine-5-carboxamide) in a specific weight ratio with a cellulose ether excipient when the composition is administered once per day with constant release of the carbamazepine derivative. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." Please see MPEP 2112.01.

Regarding instant claim 4, the limitation of hydroxypropyl methyl cellulose is anticipated by the HPMC (Col. 8, lines 52-54), as taught by Katzhendler.

Regarding instant claim 6, the limitation of ethyl cellulose is anticipated by the ethylcellulose (Col. 9, lines 45-52), as taught by Katzhendler.

Therefore, the limitations of claims 18, 4 and 6 are anticipated by the teachings of Katzhendler.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 8-9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzhendler et al. (US 6,296,873) in view of Eibl et al. (US 5,290,769).

Katzhendler teaches that the polymeric matrix of the drug delivery system may also contain hydrophobic polymers such as methacrylic acid derivatives (Col. 9, lines 45-52).

Katzhendler does not expressly teach a polymethacrylates which is trimethylammonium methacrylate.

Eibl teaches tablet dosage forms (Col. 2, lines 1-2) and further teaches coating substances including copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate (for example EUDRAGIT ® RL) (Col. 6, lines 23-25). Auxiliary substances including microcrystalline cellulose used as disintegrants are also disclosed (Col. 6, lines 13-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a sustained release tablet of oxcarbazepine with methacrylic acid derivatives, as suggested by Katzhendler, and combine it with the copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate (for example EUDRAGIT ® RL), as suggested by Eibl, with a reasonable expectation of producing a sustained release tablet of oxcarbazepine.

One with ordinary skill in the art would have done so because copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate are known in the art as coating substances that are used in the production of delayed or sustained release dosage forms.

Regarding instant claim 8, the polymethacrylates which is trimethylammonium methacrylate would have been obvious over the copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate, as taught by Eibl (Col. 6, lines 23-25).

Regarding instant claim 9, the microcrystalline cellulose would have been obvious over the microcrystalline cellulose taught by Eibl (Col. 6, lines 13-17).

23. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzhendler et al. (US 6,296,873).

Katzhendler teaches the dissolution testing of the drug delivery system that illustrates a greater than 80% release of drug in 1 hour of the test (see Figure 7). A 1% sodium dodecyl sulfate solution in water was used (Col. 19, lines 15-19).

Katzhendler does not expressly teach that the drug delivery system has an 80% or greater release of the oxcarbazepine dose within 1 hour indicated in standard in vitro dissolution tests at 37 degrees Celsius in water using sodium dodecyl sulphate as a solubilizing agent at a concentration of 1% for a 600 mg dosage form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a sustained release tablet of oxcarbazepine with HPMC and ethyl cellulose, as suggested by Katzhendler, test the dosage form using the established in vitro dissolution tests according to the current pharmacopeial standards, and produce the instant invention.

Since the components of the composition (drug, excipient, ratio of excipient:drug) and the administration of the composition (once per day) are taught by Katzhendler, the in vitro dissolution testing of the composition with the specific temperature and dosage would have been obvious to one of ordinary skill in the art over the current pharmacopeial standards.

Regarding instant claims 10-12, the recited release rates of oxcarbazepine would have been obvious variants over the dissolution rates disclosed by Katzhendler (Figure 7, Figure 9).

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 4, 6, 8-12 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 12-13 and 15-16 of copending Application No. 10/598,553 ('553 hereinafter) in view of Katzhendler et al. (US 6,296,873).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference is that instant claims are drawn to oxcarbazepine (10,11-Dihydro-10-oxo-5*H*-dibenz[*b,f*]azepine-5-carboxamide) and claims of '553 are drawn to 10,11-Dihydro-10-hydroxy-5*H*-dibenz[*b,f*]azepine-5-carboxamide. Katzhendler

teaches oxcarbazepine and the mono hydroxy derivative (MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) as the pharmaceutical active agents (Col. 3, lines 64-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to make an oral, controlled release dosage form with either oxcarbazepine or the mono hydroxy derivative because both active agents are disclosed by Katzhendler.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 4, 6, 8-12 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 6-7, and 9-12 of copending Application No. 10/598,786 ('786 hereinafter) in view of Katzhendler et al. (US 6,296,873).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference is that instant claims are drawn to oxcarbazepine (10,11-Dihydro-10-oxo-5*H*-dibenz[*b,f*]azepine-5-carboxamide) and claims of '786 are drawn to 10,11-Dihydro-10-hydroxy-5*H*-dibenz[*b,f*]azepine-5-carboxamide (licarbazepine). Katzhendler teaches oxcarbazepine and the mono hydroxy derivative (MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) as the pharmaceutical active agents (Col. 3, lines 64-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to make an oral, controlled release dosage form with either oxcarbazepine or the mono hydroxy derivative because both active agents are disclosed by Katzhendler.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

27. No claims are allowed.

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615